

REMARKS/ARGUMENTS

By the foregoing amendment, independent claim 53 has been amended to eliminate recitation of “marker circuitry” and dependent claims 62 and 63 have been amended to correct their dependency. No new matter has been added.

In the office action, the Examiner withdrew claims 53-57, 62 and 63 from consideration as being directed to an invention that is patentably distinct from the previously claimed invention insofar as the claims recited “marker circuitry.” Applicant notes that, in view of the filing of an RCE to compel entry of the amendment, it was within the Examiner’s discretion to consider claims 53-57, 62 and 63 irrespective of whether Applicant was entitled to examination of the amended claims “as a matter of right.” MPEP § 706.07(h). However, the issue is now moot in view of the foregoing amendment removing the specific limitation of “marker circuitry” from the claims.

As amended, independent claim 53 recites a system that includes the following:

- 1) a catheter body;
- 2) a single tissue penetrating element having a lumen, a tissue penetrating distal tip and a distal end opening, said tissue penetrating element being alternately disposable in a) a first position wherein the tissue penetrating element is substantially within the catheter body and b) a second position wherein the tissue penetrating element assumes a predetermined curved configuration and extends out of an opening formed in the side wall of the catheter body so as to penetrate a wall of the blood vessel adjacent to the blood vessel lumen in which the catheter is positioned;
- 3) a guidewire that is advanceable through the lumen of the tissue penetrating element while the tissue penetrating element is in the second position;
- 4) an imaging apparatus on or in the catheter body and useable to image the target location; and

5) an image display apparatus adapted to display an image received from the imaging apparatus in combination with an indication of the trajectory on which the tissue penetrating element is expected to ~~will~~ subsequently advance while the tissue penetrating element is still in the first position, thereby facilitating adjustment of the rotational orientation of the catheter body within the blood vessel while the penetrating element is in the first position so that subsequent advancement of the tissue penetrating element to the second position will cause the tissue penetrating element to advance in the direction of the target location.

In the preceding final Office Action, new grounds for rejection were raised, rejecting all claims 53-58 and 61-63 over United States Patent No. 5,464,395 (Faxon et al.) in combination with United States No. 5,749,848 (Jang et al.). In view of the fact that new grounds for rejection were raised, Applicant does not believe that it was proper or fair for the rejection to have been made final. Applicant reserves the right to file a petition un Rule 181 seeking withdrawal of the finality of the office action in the event that the present amendment is refused entry.

The final Office Action states at page 4 that Jang et al. inherently describes one or more imageable markers useable in conjunction with an imaging apparatus. Applicant disagrees. The law on inherency has been succinctly stated by the United States Court of Appeals, as follows:

To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added)

Stated another way, "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly

inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) In *Levy* the Board considered a claim directed to a balloon catheter having a biaxially oriented balloon. The examiner had rejected that claim over a prior art patent that disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow molding). The reference did not directly state that the end product balloon was biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." Id. at 1462. The examiner had argued that the prior art balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.

In this case, the record contains no extrinsic evidence and no reasoning whatsoever to establish that Jang et al. must *necessarily* include the "maker and imager" as the Examiner contends. Thus, Applicant respectfully submits that inherency has not been established.

Irrespective of whether Jang et al. inherently discloses an imageable marker or not, the presently amended claims are patentably distinguishable over Faxon et al., Jang et al. and all other prior art of record. Neither Faxon et al. nor Jang et al. describe or render obvious a system that includes the 5 elements recited in claim 53. Thus, the subject matter of independent claim 53 is allowable over the cited combination of Faxon et al. and Jang et al. even if the Examiner does not withdraw the rejection due to non-inherency in accordance with *Ex parte Levy*, supra, Dependent claims 54-57 and 62-63 further define the subject matter of claim 53 and are also allowable on at least the same grounds as claim 53 and possibly other grounds not specifically articulated here.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5484.

Respectfully submitted,

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